K051374

Appendix 1 - 510(k) Summary of Safety and Effectiveness

JUN 2 3 2005

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Device description	The Cardiodrive® advances or retracts a compatible magnetic electrophysiology [EP] catheter, through a hemostasis introducer, remotely via a User Interface (UI) located either at the patient table or in the control room.
Intended use	The Stereotaxis Cardiodrive® is intended for automatically advancing and retracting only the Stereotaxis Tangent® Electrophysiology Catheter (part #001-001223-1) of 7F shaft diameter and 8F tip. The Cardiodrive® is intended to advance the Stereotaxis Tangent® Electrophysiology Catheter in the right side of the heart only. It is not intended to advance the Tangent® Electrophysiology Catheter through the coronary vasculature nor the coronary sinus.
Technological characteristics	The Stereotaxis Cardiodrive® consists of an electrical controller, motor assembly, and user controls, plus sterile, single-use advancer unit, horizontal patient mounting bracket, flexible drive shaft, and hemostasis introducer adapter.
Device comparisons	The modified Stereotaxis Cardiodrive® consists of minor design modifications of the currently marketed Stereotaxis Cardiodrive®. The new Cardiodrive® has a modified Hemostasis Introducer Adapter and a new horizontal patient mounting bracket to better accommodate the use of larger guiding sheaths.

Continued on next page

K051374

Appendix 1 - 510(k) Summary of Safety and Effectiveness, Continued

JUN 2 3 2005

Physical testing	The Stereotaxis Cardiodrive® was designed and tested in compliance with Stereotaxis design control procedures. The device met design input criteria and was substantially equivalent to the currently marketed predicate device.
Performance data	Bench testing and pre-clinical testing demonstrate that the Stereotaxis Cardiodrive® performs in an equivalent manner to the currently marketed Cardiodrive® predicate device.
Clinical performance data	No clinical studies were needed to support the modifications described herein.
Conclusion	The modified Cardiodrive® is substantially equivalent to the Cardiodrive® (K021802) predicate device. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device.
Contact	Kelly Rowland Regulatory Affairs Specialist
Date	May 6, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2005

Stereotaxis, Inc.
c/o Ms Kelly Rowland
Regulatory Affairs Specialist
4041 Forest Park Avenue
St Louis, MO 63108

Re: K051374
Trade Name: Cardiodrive Catheter Advancement System
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II (two)
Product Code: DQX
Dated: May 24, 2005
Received: May 26, 2005

Dear Ms. Rowland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2 - Indications for Use Statement

Statement

510(k) Number (if known): K 051374

Device Name: Cardiodrive® Catheter Advancement System (CAS)

Indications for Use: The Stereotaxis Cardiodrive® is intended for automatically advancing and retracting only the Stereotaxis Tangent® Electrophysiology Catheter of 7F shaft diameter and 8F tip. The Cardiodrive® is intended to advance the Stereotaxis Tangent® Electrophysiology Catheter in the right side of the heart only. It is not intended to advance the Tangent® Electrophysiology Catheter through the coronary vasculature nor the coronary sinus.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

Page 1 of 1

510(k) Number K051374